### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

(Attorney Docket No. 06401.00418)

In re application of:	)
Lin Wang	) Group Art Unit: 1732
Serial No: 10/687,498	) Examiner: Monica A. Huson
Filed: March 25, 2004	) Confirmation No.: 9050
For: Process Using Cold-Water Soluble Extruded Starch	) ) )

### **BRIEF ON APPEAL**

Customer Service Window 401 Dulany Street Alexandria, VA 22314

Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant submits this Appeal Brief to the Board of Patent Appeals and Interferences in response to the Final Office Action mailed April 23, 2007. A Notice of Appeal was timely filed on July 23, 2007.

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# I. Real Party in Interest

The real party in interest is Grain Processing Corporation, the owner of the entire right, title and interest in and to the subject application.

## II. Related Appeals and Interferences

An Appeal Brief and subsequent Reply Brief have been filed in co-pending parent application Serial No. 09/863,928.

## III. Status of the Claims

Claims 1-7 are under appeal and stand finally rejected. No claim is allowed. Claims 1-7 are found in the Appendix.

No amendment after final rejection has been filed.

### V. Summary of Claimed Subject Matter

The subject matter of independent claim 1 is directed to a process for preparing a film (specification paragraph [0029].) The film is prepared from a solution of an extruded starch product (specification paragraph [0018].) The starch product is prepared by a process comprising providing a hydroxyalkyl starch, the starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms (specification paragraph [0017].) The starch is extruded in an extruder (specification paragraph [0018].) The extruder has a barrel, a die, and at least one rotating shaft (specification paragraph [0008].) The barrel has at least first and second zones, the first zone being upstream from the second zone (specification paragraph [0008].) The temperature in the first zone is insufficient to gelatinize the starch to a gelatinization level of at least 95% and the temperature in the second zone being sufficient to gelatinize the starch to a gelatinization level of at least 95% (specification paragraphs [0019] and [0022].) The starch is extruded in the presence of total moisture in said barrel no greater than about 25% by weight of said starch (specification paragraph [0018].) The process includes the step of controlling the rotational speed of said shaft to impart a specific mechanical energy to the starch sufficient to result in a soluble extruded starch product that is capable of extrusion through said die at said rotational speed, the solution having been prepared by mixing said starch product with water (specification paragraph [0020].) A film is formed from the solution (specification paragraph [0029].)

## VI. Grounds of Rejection to be Reviewed on Appeal

Rejection 1: Claims 1-6 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent No. 4,076,846 to Nakatsuka *et al.* ("Nakatsuka") and U.S. Patent No. 5,849,233 to Altieri ("Altieri").

Rejection 2: Claim 7 stands rejected under § 103(a) as being obvious in view of Nakatsuka and Altieri as well as U.S. Patent No. 5,455,342 to Redding, Jr. ("Redding, Jr.").

#### VII. Argument

An obviousness rejection under 35 U.S.C. § 103 is appropriate only when the differences between the claimed invention and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." *In re Dembiczak*, 175 F.3d 994, 50 U.S.P.Q.2d 1614, 1616 (Fed. Cir. 1999); 35 U.S.C. § 103(a). The ultimate determination of whether an invention would have been obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) any objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

The USPTO has issued guidelines to its Examiner's dealing with obviousness rejections. The notice points out that the KSR (KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1734, 82 USPQ2d 1385, 1391 (2007), reaffirmed the analytical framework for obviousness that was presented in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). In that connection, PTO personnel serve as factfinders with respect to the following:

- 1. Determining the scope and content of the prior art;
- 2. Ascertaining the difference between the claimed invention and the prior art; and
- 3. Resolving the level of ordinary skill in the art

When making an obviousness rejection, the notice states, examiners must ensure that the written record includes not only findings on those points, but also explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. "Factual findings made by Office personnel are the necessary underpinnings to establish obviousness," according to the PTO. This is important, the

notice added, regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense.

The clear articulation of the reason(s) why the claimed invention would have been obvious is key to supporting any rejection under 35 U.S.C. 103, according to the notice. Under KSR, it explained, the analysis supporting an obviousness rejection should be made explicit. KSR said such rejections "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness," quoting *In re Kahn*, 441 F.3d 977, 78 USPQ2d 1329 (Fed. Cir. 2006).

The rejection over the instant claims does not provide an "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Such rational underpinning simply cannot exist because none of the cited documents teach or suggest elements of the claims and actually teach away from the instant claims as explained below.

#### Rejection 1: Nakatsuka and Altieri do not teach or suggest claims 1-6.

### 1. <u>Nakatsuka does not disclose a starch product</u>

Nakatsuka is directed towards the formation of a complex of starch with a protein.

Nakatsuka identifies starch as a *starting material* along with a protein, but does not identify starch as the material that results upon extrusion. In fact, Nakatsuka does not specify the nature of the product formed thereby. Nakatsuka does not indicate whether the product is a starch or a protein, or whether the resulting material even has any polymeric carbohydrate structure.

Throughout the Final Office Action, the *starting materials* disclosed by Nakatsuka are consistently and repeatedly confused with the products formed by extrusion. This error

permeates the reasoning in the rejections and is of particular relevance to the claimed "extruded starch product."

Nakatsuka's product is not an "extruded starch product." In Nakatsuka's own words, the complex formed upon extrusion of starch with protein "is not a simple mixture," but rather "it seems that some degree of union has been established between both materials by chemical reaction, thus contributing to the improvement in physical properties." Column 6, lines 33-40. Whatever this product is, it is not a starch product. It is irrelevant that Nakatsuka teaches starch as a starting material.

The Final Office Action pointed to Column 11, lines 1-6 in Nakatsuka to support its position. Here, Nakatsuka states that the article thus formed is a "starch-protein binary blend." This teaching confirms that the error in the Final Office Action – i.e., that "some degree of union has been established between [starch and protein] by chemical reaction." Nakatsuka's disclosure of a starch-protein complex is insufficient to meet the claims.

#### 2. <u>Nakatsuka does not disclose or suggest the claimed extrusion conditions</u>

Nakatsuka fails to teach extruding the starch in an extruder having two zones, as specified in the claims. Claim 1 specifies that the temperature in the first zone of the extruder is *insufficient* to gelatinize the starch but that the temperature in the second zone is *sufficient* to gelatinize the starch. This teaching is not present in Nakatsuka. The claimed extrusion conditions are simply nowhere to be found in the Nakatsuka.

The Final Office Action erroneously purports to find these conditions in Nakatsuka:

Nakatsuka clearly discloses an extruder barrel having at least two zones at Column 13, lines 34-37. As previously noted, gelatinization occurs at about 150C-175C, so it is being interpreted that the cooler first zone would be insufficient to gelatinize the molding material, while the subsequent second/third

zone would be sufficient for gelatinization. Note it is being interpreted that since Nakatsuka does disclose that gelatinization is effected via his process (Column 6, lines 14-19), 100% gelatinization occurs while or after the molding composition material is in the second/third zone."

In the passage relied on above, Nakatsuka refers to gelatinization of starch *in the starting materials*, not upon extrusion. Moreover, since Nakatsuka discloses that starch was gelatinized before extrusion, the concept of a first barrel zone at a temperature insufficient to gelatinize as recited in claim 1 would be inapplicable.

As noted above, the material prepared after extrusion by Nakatsuka is described as a starch-protein complex or "binary blend," and it is unclear whether any carbohydrate structure exists. It is further unclear whether the concept of a gelatinization temperature is at all applicable or relevant to this material. If the material is capable of gelatinization, it is unknown whether the conditions specified by Nakatsuka would meet the claimed requirements. Nakatsuka simply does not disclose or suggest the claimed extrusion conditions.

#### 3. Nakatsuka does not teach "forming a film from said solution."

Nakatsuka discloses a molding process and a blend of starting materials as a "molding composition." This molding composition is treated to produce molded or shaped articles.

The claims are drawn towards a process for preparing a film, including *forming a film* from a solution of the extruded starch product. Nakatsuka is completely silent as to forming a film. The sole place in Nakatsuka where film forming is said to be disclosed is the Abstract, but the Abstract does not disclose the formation of a film.

#### 4. Altieri does not remedy the defects of Nakatsuka

Altieri is relied on to show specific barrel moisture levels. However Altieri does not Serial No. 10/687,498

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remedy the defects of Nakatsuka. Altieri does not suggest modifying the starting materials of Nakatsuka to provide a starch product. Nor does Altieri suggest modifying Nakatsuka to provide two zones wherein the temperature in the first zone of the extruder is insufficient to gelatinize the starch but that the temperature in the second zone is sufficient to gelatinize the starch. Finally, as recognized in the Final Office Action, Altieri describes a molded product and not a film as claimed. Hence, Altieri does not remedy this defect of Nakatsuka.

Nakatsuka and Altieri do not teach or suggest independent claim 1. Hence claim 1 is allowable over Nakatsuka and Altieri. Dependent claims 2-6 are likewise allowable over Nakatsuka and Altieri for at least the same reasons applicable to independent claim 1. It is respectfully requested that the rejection of claims 1-6 over Nakatsuka in view of Altieri be reversed.

### Rejection 2: Nakatsuka, Altieri, and Redding, Jr. do not teach or suggest claim 7

Claim 7 depends on claim 1. Nakatsuka and Altieri do not teach or suggest independent claim 1 for the reasons identified above. Redding, Jr. does not remedy the defects of Nakatsuka and Altieri.

#### 1. Redding, Jr. teaches away from Nakatsuka

Nakatsuka and Redding, Jr. are incompatible. Redding, Jr. emphasizes the undesirability of chemically modifying starch, (see Column 2, line 30 et seq.), and teaches that one of the objects of the invention is "to provide a cost effective and energy efficient method of physical modification of starch and other substrates without the necessity of chemical additives," (Column 3, lines 46-49; emphasis added). (Column 2, lines 3-16).

Nakatsuka, on the other hand, teaches a modified "mixture of a starch material and a neutral inorganic salt of a protein . . . [wherein] some degree of union has been established between both materials," (Column 6, lines 34-40), and further teaches that the crosslinking between the starch material and the protein salt may be accelerated through ultraviolet irradiation, (Column 10, lines 10-17). Nakatsuka is therefore completely antithetical to Redding, Jr. -- one reference teaches to modify the starch heavily, the other teaches that chemical modifications to starch are not desirable and should be avoided.

The Final Office Action points to Column 2 of Nakatsuka, in which Nakatsuka teaches that the starch starting material should not be modified. Again, there is confusion between the starting material of Nakatsuka and the final product of Nakatsuka. The whole point of Nakatsuka is to modify the starch starting material very heavily with a protein. This teaching is not compatible with that of Redding, Jr.

### 2. <u>Nakatsuka and Redding each teach away from hydroxyalkyl starches</u>

As recognized by the Final Office Action, Nakatsuka teaches away from starting with a starch starting material that has been modified. Nakatsuka therefore teaches away from the hydroyalkyl starch specified in the claims.

Redding, Jr. also teaches away from starch modification and specifically from hydroxyalkyl starches. Redding, Jr. reports that prior art starches include substituted starches, and that known substituents include "acetate, succinate, phosphate, hydroxypropyl, and octenylsuccinate." According to Redding, Jr., "[e]ach of the above modification processes, however, suffer from various shortcomings and result in starch products with physical property

limitations." Only in hindsight would someone ignore these contrary teachings and employ a hydroxyalkyl starch.

Nakatsuka, Altieri, and Redding, Jr. do not teach or suggest claim 7. Hence claim 7 is allowable over Nakatsuka, Altieri, and Redding, Jr. It is respectfully requested that the rejection of claim 7 over Nakatsuka, in view of Altieri and Redding, Jr. be reversed.

### **Summary of Arguments**

Several claim elements are not found in any of the cited references. Specifically, the references fail to teach or suggest "a solution of an extruded starch product" or "forming a film." Nor do the references teach or suggest "an extruder having a barrel... said barrel having at least first and second zones" where the temperature in the first zone is insufficient to gelatinize the starch but the temperature in the second zone is sufficient. Moreover, the cited references teach away from one another and from the claimed invention and the cited references teach away from the claimed hydroxypropyl starch. Reversal of the rejections is respectfully requested.

#### VIII. Conclusion

For reasons argued above, the Final Office Action has failed to set forth a *prima facie* case of obviousness of claims 1-7. Reversal of the obviousness rejections and allowance of the subject application are respectfully requested.

Respectfully submitted,
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Date: February 25, 2008

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#### CLAIMS APPENDIX

1. A process for preparing a film, comprising:

providing a solution of an extruded starch product, said starch product having been prepared by a process comprising

providing a hydroxyalkyl starch, said starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms; and

extruding said starch in an extruder, said extruder having a barrel, a die, and at least one rotating shaft, said barrel having at least first and second zones, said first zone being upstream from said second zone, the temperature in said first zone being insufficient to gelatinize said starch to a gelatinization level of at least 95% and the temperature in said second zone being sufficient to gelatinize said starch to a gelatinization level of at least 95%, said starch being extruded in the presence of total moisture in said barrel no greater than about 25% by weight of said starch, said process including the step of controlling the rotational speed of said shaft to impart a specific mechanical energy to said starch sufficient to result in a soluble extruded starch product that is capable of extrusion through said die at said rotational speed;

said solution having been prepared by mixing said starch product with water; and forming a film from said solution.

- 2. A process according to claim 1, the moisture in said barrel not having exceeded 22.5% by weight of said starch.
- 3. A process according to claim 1, the moisture in said barrel not having exceeded 20% by weight of said starch.
- 4. A process according to claim 1, the moisture in said barrel not having exceeded 17.5% by weight of said starch.
  - 5. A process according to claim 1, wherein said solution includes a plasticizer.

- 6. A film formed in accordance with the process of claim 1.
- 7. A process according to claim 1, said starch having been a granular starch having a particle size distribution such that at least 90% by weight of the starch particles pass through a 180 micron screen.

## **EVIDENCE APPENDIX**

None submitted.

## RELATED PROCEEDINGS APPENDIX

No final decisions have been rendered in related proceedings.					